K132992

DEC 18 2013

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 12th September 2013

5.3 Submitter:

T-PLUS Implant Tech. Co., Ltd.
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Contact: Dana Cheng (tplus.dana@gmail.com)

5.4 Identification of the Device:

Proprietary/Trade name:	Ti Star Implant System
Classification Name:	Endosseous Dental Implant System
Device Classification:	II
Regulation Number:	872.3640
Panel:	Dental
Product Code:	DZE, NHA

5.5 Identification of the Predicate Device:

Predicate Device Name:	ExFeel Implant System
Manufacturer:	MegaGen Co., Ltd.
Product Code:	DZE
510(k) Number:	K052369

5.6 Intended Use and Indications for Use of the subject device.

The Ti Star Implant System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

The Ti Star Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

5.7 Device Description

The Ti Star Implant System is an integrated system of endosseous dental implants which designed to support prosthetic devices for partially or fully edentulous patients. Ti Star Implant System consist of one-stage and two-stage, root form dental implants, associated with abutment systems, which provide the dentist with screw and cement retained restoration options. The devices covered by this submission are Ti Star Implant Fixtures, abutments, cover screw, closing screw and healing screw. The diameters of implant fixture are 3.5mm, 4.1mm and 4.8mm, the lengths are 7.0mm, 8.5mm, 10.0mm, 11.5mm, 13.0mm and 15.0mm.

5.8 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of the Ti-Star Implant Systems.

Testing Item	Standard and regulations applied
Biomechanical testing	ISO 14801:2007 Dentistry. Implants. Dynamic fatigue test for endosseous dental implants
Sterilization	ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
	ISO 11737-2:2009 Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

	ISO 11137-2:2012 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
	ISO 17665-1:2006 Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. (Sterility)
	ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1. (Sterility)
Surface and material	ASTM E3 - 11 Standard Guide for Preparation of Metallographic Specimens
	ASTM F746-04 Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials. (Materials)
	ISO 16700 Microbeam analysis -- Scanning electron microscopy -- Guidelines for calibrating image magnification
	ASTM F67-06, Standard Specification for Unalloyed Titanium for Surgical Implant Applications
	ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).
	ASTM F1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages. (Sterility)
	ASTM F1929-98(04) Standard test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
	ASTM F88 2007 Standard Test Method for Seal Strength of Flexible Barrier Materials
	ASTM F1980-07 Standard Guide for Accelerated Aging

	of Sterile Barrier Systems for Medical Devices
	ASTM F88/F88M 2009 Standard Test Method for Seal Strength of Flexible Barrier Materials

All the test results demonstrate Ti Star Implant System meets the requirements of its pre-defined acceptance criteria and intended uses.

5.9 Clinical Testing

No clinical test data was used to support the decision of safety and effectiveness.

5.10 EMC and Electrical safety

The devices do not require EMC/Electrical Safety evaluation.

5.11 Substantial Equivalence Determination

The Ti Star Implant Systems submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared ExFeel Implant System (K052369). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

	Proposed Device	Predicate Device
Item	Ti Star Implant System	ExFeel Implant System (K052369)
Classification	Class II	Class II
Product Code	DZE、NHA	DZE
Intended Use	The Ti Star Implant System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. The Ti Star Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure
Consisted Instruments	1. Fixture 2. Various abutments and components	1. Fixture 2. Various abutments and components
Material	C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy
Implant type	Threaded, screw type, root-form, fixation, tapered, internal and morse taper	Internal, External Hex and Morse Taper
Implant to abutment connection	Internal Octa Connection	Internal Octa Connection

Implant surface treatment		RBM	RBM
Dimensions (mm)	Diameter	3.5、4.1、4.8	3.5、4.1、4.8
	Length	7.0、8.5、10.0、11.5、13.0、15.0	7.0、8.5、10.0、11.5、13.0、15.0
Sterilization		Gamma irradiation	Gamma irradiation
Design/technical characteristics of the abutment			
Abutment material		Gr.4、Gr.5	Gr.3、Ti6AlV、ELI Gr.23、SUS316L
Collar heights (mm)		2.2	2.2
Abutment System		Multi-mount、Solid、Solid Post、Ez Post	Multi-mount、Octa、Solid、Ez Post、Esthetic, Mirus, Widecone、Standard
Abutment angle		--	--

5.11 Similarity and differences

The only difference between the subject device and predicate device is on the grade of C.P Titanium and Titanium Alloy. The predicate devices were Gr.3, Ti6AlV, ELI Gr.23 and SUS316L. The materials of subject device were Gr.4 and Gr.5. The subject device has tested on safety and performance tests and the test results were complied with the test requests. Therefore, the difference of subject device and predicate device didn't raise any problems of safety or effectiveness. The proposed device is substantially equivalent to the predicate device in design, operation, intended use, method of preparation, and performance claims.

5.12 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that Ti Star Implant System is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

T-PLUS Implant Tech Company, Limited
Ms. Dana Cheng
Quality Assurance
No. 41, Wuquan 6th Rd. Wugu Dist.,
New Taipei City
TAIWAN

Re: K132992
Trade/Device Name: Ti Star Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant System
Regulatory Class: II
Product Code: DZE
Dated: November 28, 2013
Received: November 29, 2013

Dear Ms. Cheng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Ti Star Implant System

Indications for Use: K132992

The Ti Star Implant System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

The Ti Star Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S
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